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Regulatory Directive DIR2010-02

Label Improvements for Spot-on Pesticides Used for Flea and Tick Control on Companion Animals

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The purpose of this document is to outline recent label improvements required for spot-on pesticides used on companion animals. The improvements are intended to reduce the potential for misuse of these pesticide products, thereby protecting animal and human health. It is anticipated that these measures will be a positive step towards reducing the number of incidents that may occur from use of these products.

This document should be used in concert with Regulatory Directive DIR2002-01, *Canadian Label Improvement Program for Pesticides Used on Companion Animals.*

1.0 Background

Recently, Health Canada's Pest Management Regulatory Agency (PMRA) received incident reports that suggested that there may be a potential for adverse reactions in cats and dogs from the use of dermally applied flea and tick control products. The majority of products involved spot-on products. An advisory was issued in April 2009 reminding consumers to follow label directions for these products. This advisory was followed by an in-depth analysis of the incident reports received by the PMRA. An update to the advisory was released in March 2010 summarizing the results of the full analysis.

As a result of the analysis, the PMRA is taking immediate action to strengthen the label of these products. The required changes are identified in this Directive. Registrants have been consulted on these changes.

The PMRA is also pursuing additional activities to mitigate risk including, but not limited to, increasing public awareness and improvements to protocols used to assess safety to pets. These activities are not discussed in this document.

2.0 Label Amendments

2.1 For spot-on products <u>not</u> containing the active ingredient Permethrin (including those for cats and dogs)

a. Under Precautions, Pets: The following wording is to be added "Care should be taken to prevent exposure of other pets who may be in close physical contact with the treated animal."

2.2 For spot-on products containing the active ingredient Permethrin

a. On the primary Panel, a pictogram is to be added of a cat's silhouette within a red circle with a diagonal line through the picture of the cat.
    i. The pictogram is to be the same size and in the same location as symbols used to identify hazard
    ii. Underneath the pictogram, the words "Toxic to cats" are to be added

b. Under Precautions, Pets (secondary panel, insert): The existing statement "Cats that actively groom or engage in close physical contact with recently treated dogs may be at risk of harm" is to be replaced with the following: "Cats that actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harm, including death."

2.3 For all flea and tick spot-on products

a. Under Precautions, Pets (secondary panel, insert): The following wording is to be added after the statements required under 2.1 or 2.2: "Sensitivities may occur after using any pesticide for pets. Smaller animals are more likely to experience an adverse reaction. Observe carefully."

b. The wording "Sensitivities may occur after using any pesticide for pets." in the First Aid, Pets section is no longer required as it will now be stated in the Precautions, Pets section.

3.0 Implementation

Registrants are required to make the changes to their labels immediately. To facilitate the changes and minimize the regulatory burden, the PMRA will make the appropriate changes to the product label via a PMRA Label Improvement notification. Registrants will be given 12 months from the date of notification to distribute or sell product with the previously approved label to allow product to clear channels of trade. Any inquiries should be directed to the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).